

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESale PRICE
LITIGATION

THIS DOCUMENT RELATES TO:
State of Iowa v. Abbott Laboratories, et al.

MDL No. 1456
Master File No.: 01-CV-12257-PBS
(original S. D. Iowa No. 4:07-cv-00461-
JAJ-CFB)

Judge Patti B. Saris

**ANSWER AND AFFIRMATIVE DEFENSES OF IVAX CORPORATION AND
IVAX PHARMACEUTICALS, INC. TO THE STATE OF IOWA'S COMPLAINT**

Defendants Ivax Corporation ("Ivax") and Ivax Pharmaceuticals, Inc. ("IPI"), by and through their attorneys, hereby state as an Answer and Affirmative Defenses to the State of Iowa's Complaint, dated October 9, 2007, as follows:

Preliminary Statement

Ivax and IPI explicitly deny the existence of, or their participation in, any fraud, fraudulent scheme, conspiracy, or enterprise. Ivax and IPI further deny each and every allegation contained in the Complaint, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to specific facts and not as to any conclusions, characterizations, implications, innuendoes, or speculations which are contained in any averment or in the Complaint as a whole. Ivax and IPI specifically deny any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, Ivax and IPI have included in this Answer and Affirmative Defenses certain captions used in the Complaint, but specifically denies any allegations contained in, or inferences that could be drawn from, those captions.

I. INTRODUCTION

1. Ivax and IPI admit that the State of Iowa (the “State”) seeks to bring this action as alleged in Paragraph 1 of the Complaint, but Ivax and IPI deny that there is any basis for the State to do so and denies that the State is entitled to any relief.

2. Ivax and IPI deny the allegations set forth in Paragraph 2 to the extent they are directed at Ivax and IPI. Ivax and IPI specifically deny that they “purposefully report[s] false and inflated price information.” To the extent the allegations in Paragraph 2 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

3-4. Ivax and IPI deny the allegations set forth in Paragraphs 3 and 4 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they submit “false and inflated pricing information in order to ‘create a spread.’” Ivax and IPI further deny the characterization of “spread” in Paragraphs 3 and 4. To the extent the allegations in Paragraphs 3 and 4 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

5. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5.

6. Ivax and IPI deny the allegations set forth in Paragraph 6 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they “purposefully manipulate[s] a market that, by defendants’ own design, is extremely complicated and non-transparent.” To the extent the allegations in Paragraph 6 are directed at parties

other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

7-8. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 7-8.

9. Ivax and IPI deny the allegations set forth in Paragraph 9 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they engaged in any “unlawful price reporting activity [that] infects all four [pricing] benchmarks and renders each of them false and inflated.” To the extent the allegations in Paragraph 9 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

10. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10, except that they admit that they pay Medicaid rebates to Iowa and that such rebates lower the price Iowa Medicaid pays for prescription drugs from Ivax and IPI. To the extent the allegations in Paragraph 10 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

11. Ivax and IPI deny the allegations set forth in Paragraph 11 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they do not accurately report Best Prices. To the extent the allegations in Paragraph 11 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

12. Ivax and IPI deny the allegations set forth in Paragraph 12 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they engage in “unlawful pricing schemes,” the “manipulation of the Medicaid program” or the “improper reporting of false and inflated pricing information” resulting in “overcharges . . . to the Iowa Medicaid Program.” To the extent the allegations in Paragraph 12 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

13. Ivax and IPI deny the allegations set forth in Paragraph 13 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they engage in “wrongful practices” that have a “pernicious . . . effect on the public fisc.” To the extent the allegations in Paragraph 13 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

14-15. Ivax and IPI admit that they voluntarily participate in the Iowa Medicaid program, but deny that they have violated any State or Federal law. To the extent the allegations in Paragraphs 14 and 15 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 14 and 15 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

16. Ivax and IPI deny the allegations set forth in Paragraph 16 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they “intentionally report false prices to the government.” To the extent the allegations in Paragraph 16 are

directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

17. Ivax and IPI deny the allegations set forth in Paragraph 17 to the extent they are directed at Ivax and IPI. Ivax and IPI specifically deny that they engage in “fraudulent, unfair and deceptive practices.” To the extent the allegations in Paragraph 17 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

18. Ivax and IPI admit that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but deny any liability to Plaintiff with respect to any such NDCs. To the extent the allegations in Paragraph 18 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

II. PARTIES

19. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19. To the extent the allegations in Paragraph 19 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

20. Ivax and IPI deny the allegations set forth in Paragraph 20 to the extent they are directed at Ivax and IPI, except Ivax and IPI admit that they manufacture and sell prescription drugs and that they participate in the Iowa Medicaid Program. To the extent

the allegations in Paragraph 20 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

21. Ivax and IPI admit that they conduct business in the State of Iowa. To the extent the allegations in Paragraph 21 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

22-38. The allegations in Paragraphs 22 through 38 are directed to other Defendants and require no response from Ivax or IPI. To the extent a response is deemed to be required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 22 through 38.

39. Ivax and IPI respond to the allegations in Paragraph 39 as follows:

- (a) Ivax and IPI admit that Ivax Corporation is a Florida corporation and admit its principal place of business, but deny that Ivax Corporation is engaged in the business of manufacturing and selling pharmaceuticals.
- (b) Ivax and IPI admit that Ivax Pharmaceuticals, Inc. is a Florida corporation and admit its principal place of business. Ivax and IPI further admit Ivax Pharmaceuticals, Inc. is engaged in the business of manufacturing and selling pharmaceuticals and is a subsidiary of Ivax Corporation.

Ivax and IPI deny the remaining allegations of Paragraph 39.

40-58. The allegations in Paragraphs 40 through 58 are directed to other Defendants and require no response from Ivax or IPI. To the extent a response is deemed to be required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 40 through 58.

III. JURISDICTION AND VENUE

59. Ivax and IPI admit that the State of Iowa purports to bring this action as alleged in Paragraph 59, but Ivax and IPI deny there is any basis for the State to do so and denies that the State is entitled to any relief.

60-61. Paragraphs 60 and 61 state legal conclusions to which no response is required. To the extent a response is deemed to be required, Ivax and IPI deny the allegations in Paragraphs 60 and 61, and note that this captioned matter has been transferred to this Court by the Judicial Panel on Multi District Litigation, pursuant to 28 U.S.C. § 1407.

IV. ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

A. The Medicaid Statutory Scheme.

62. With respect to the allegations in Paragraph 62, Ivax and IPI admit that Medicaid was established by Title XIX of the Social Security Act. Ivax and IPI further state that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.

63. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63, except Ivax and IPI admit that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 63 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

64-65. Paragraphs 64-65 state legal conclusions or characterizations of law to which no response is required. To the extent that a response is required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 64 and 65. Ivax and IPI further state that the statutes or regulations referred to in Paragraphs 64 and 65 speak for themselves, and any characterizations thereof are specifically denied.

66. Ivax and IPI admit that national drug codes are assigned to prescription drugs. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 66.

67. Paragraph 67 states legal conclusions or characterizations of law to which no response is required. To the extent a response is required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67.

68. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68. To the extent the allegations in Paragraph 68 refer to an OIG report, the report speaks for itself, and any characterizations thereof are denied.

69. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69. To the extent the allegations in Paragraph 69 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

70. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70. To the extent the allegations in Paragraph 70 refer to an OIG report, the report speaks for itself, and any characterizations thereof are denied.

71-72. Ivax and IPI deny the allegations set forth in Paragraphs 71 and 72 to the extent they are directed at Ivax and IPI. Ivax and IPI further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 71 and 72 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

73-80. Ivax and IPI denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 73 through 80 or their subsections. To the extent the allegations in Paragraphs 73 through 80 or their subsections refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

81. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81, except that Ivax and IPI admit that pricing compendia such as First DataBank and Medi-Span publish AWP's and FULs, and deny that they have any control over such prices.

82. Ivax and IPI deny the allegations set forth in Paragraph 82 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that it "purposefully and

fraudulently conceal” the “true prices” of its drugs by “claiming they are proprietary trade secrets.” To the extent the allegations in Paragraph 82 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

B. Defendants’ Corruption of all Relevant Pricing Benchmarks

83. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 83.

84. Ivax and IPI deny the allegations set forth in Paragraph 84 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they “fraudulently misrepresent” their true prices or that they report “false and inflated prices.” To the extent the allegations in Paragraph 84 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

85. Ivax and IPI deny the allegations set forth in Paragraph 85 to the extent they are directed at Ivax and IPI, except that Ivax and IPI admit that Exhibit A purports to identify total expenditures by Defendant. Specifically, Ivax and IPI deny any “unfair practices, deception, and fraud.” To the extent the allegations in Paragraph 85 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

86. Ivax and IPI deny the allegations set forth in Paragraph 86 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny conducting any “fraudulent practices.” To the extent the allegations in Paragraph 86 are directed at

parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

87-89. Ivax and IPI deny the allegations set forth in Paragraphs 87 through 89 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they reported “false and inflated” “WACs or WAC equivalents.” To the extent the allegations in Paragraphs 87 through 89 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

90-92. Ivax and IPI deny the allegations set forth in Paragraphs 90 through 92 to the extent they are directed at Ivax and IPI. Ivax and IPI further state that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraphs 90 through 92 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

93. Ivax and IPI deny the allegations set forth in Paragraph 93 to the extent they are directed at Ivax and IPI, except Ivax and IPI admit that AWP is a benchmark related to the pricing of prescription drugs.

94-98. Ivax and IPI deny the allegations set forth in Paragraphs 94 through 98 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they “either report or caused to be reported false and inflated AWP,” “false WAC or WAC equivalents,” or that Ivax and IPI “alone control[s] the false and inflated AWP that are published for their drugs.” Ivax and IPI further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood,

including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 94 through 98 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

99. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99.

100. Ivax and IPI deny the allegations set forth in Paragraph 100 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 100 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

101. Ivax and IPI deny the allegations set forth in Paragraph 101 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

102. Ivax and IPI admit that the Federal Upper Limit (“FUL”) for certain drugs are set by the Center for Medicare and Medicaid Services (“CMS”). Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 102. To the extent the allegations in Paragraph 102 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

103. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 103, and on that basis deny them.

104-107. Ivax and IPI deny the allegations set forth in Paragraph 104 through 107 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 104 through 107 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

108. Ivax and IPI deny the allegations set forth in Paragraph 108 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 108 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

109. The allegations in Paragraph 109 require no response from Ivax and IPI on the grounds that the Iowa SMAC claims have been dismissed by the Court.

C. Brand Manufacturers' Best Price Fraud

110. To the extent that Paragraph 110 states legal conclusions or characterizations of law, no response is required. To the extent a response is required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 110, and on that basis deny them.

111. Ivax and IPI admit that they have executed rebate agreements with the Secretary of Health and Human Services. Ivax and IPI state that the rebate agreements speak for themselves, and all characterizations of such agreements are denied. To the

extent the allegations in Paragraphs 111 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

112. To the extent that Paragraph 112 states legal conclusions or characterizations of law, no response is required. To the extent a response is required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 112, and on that basis deny them.

113-121. To the extent that Paragraphs 113 through 121 state legal conclusions or characterizations of law, no response is required. To the extent a response is required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 113 through 121, and on that basis deny them.

122. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 122, and on that basis deny them.

123. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 123, and on that basis deny them.

124. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 124, and on that basis deny them.

125. To the extent that Paragraph 125 states legal conclusions or characterizations of law, no response is required. To the extent a response is required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 125, and on that basis deny them.

126. Ivax and IPI deny the allegations set forth in Paragraph 126 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 126 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

127-132. Ivax and IPI deny the allegations set forth in Paragraphs 127 through 132 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraphs 127 through 132 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 127 through 132 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

V. DEFENDANTS CONCEAL THEIR TRUE PRICES

133. Ivax and IPI deny the allegations set forth in Paragraph 133 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they have participated in any “pricing scheme . . . by exacerbating the complexities of the . . . drug market.” To the extent the allegations in Paragraph 133 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

134. Ivax and IPI deny the allegations set forth in Paragraph 134 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they “purposefully conceal[s its] true prices.” To the extent the allegations in Paragraph 134 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 134 refer to the

transcript of a Congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

135. Ivax and IPI deny the allegations set forth in Paragraph 135 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 135 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

136. Ivax and IPI deny the allegations set forth in Paragraph 136 to the extent they are directed at Ivax and IPI, except Ivax and IPI admit that certain of their contracts are subject to confidentiality agreements and that Ivax and IPI do not offer discounts to certain of its customers. To the extent the allegations in Paragraph 136 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

137. Ivax and IPI deny the allegations set forth in Paragraph 137 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they “obscure[s] the true prices for their drugs with their policy of treating different classes of trade differently.” To the extent the allegations in Paragraph 137 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

138-139. Ivax and IPI deny the allegations set forth in Paragraphs 138 and 139 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they “maintain two sets of pricing records: one with the inflated prices and another with the actual prices.” To the extent the allegations in Paragraphs 138-139 are directed at

parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 138 through 139 refer to a transcript of a Congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

140-141. Ivax and IPI deny the allegations set forth in Paragraphs 140 and 141 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they “hide their real drugs prices by secretly providing free drugs and phony grants” or that they conceal their true prices “to create spreads between actual cost and reimbursement amounts . . . to influence market share.” To the extent the allegations in Paragraphs 140 and 141 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

142. Ivax and IPI deny the allegations set forth in Paragraph 142 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 142 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

143. Ivax and IPI deny the allegations set forth in Paragraph 143 to the extent they are directed at Ivax and IPI. Ivax and IPI further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraph 143 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

144-145. Ivax and IPI deny the allegations set forth in Paragraph 144 and 145 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they engaged in any “unlawful and undisclosed manipulation of the price reporting system” or caused the “publication of a false WAC,” AWP, or FUL. To the extent the allegations in Paragraphs 144 and 145 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

VI. DEFENDANTS’ MOTIVATION FOR FALSE PRICE REPORTING

146. Ivax and IPI deny the allegations set forth in Paragraph 146 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they have “caus[ed] false prices to be published.” To the extent the allegations in Paragraph 146 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

147. Ivax and IPI deny the allegations set forth in Paragraph 147 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they “submit false and inflated wholesale price information in order to create a spread.” Ivax and IPI further deny the characterization of “spread” in Paragraph 147. To the extent the allegations in Paragraph 147 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

148. Ivax and IPI deny the allegations set forth in Paragraph 148 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny that they have “corrupted the market for prescription drugs” or have “deliberately sought to create a powerful financial incentive for providers to prescribe drugs based primarily on the

spread.” Ivax and IPI further deny the characterization of “spread” in Paragraph 148. To the extent the allegations in Paragraph 148 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

149-150. Ivax and IPI deny the allegations set forth in Paragraphs 149 and 150 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraphs 149 and 150 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

151-152. Ivax and IPI deny the allegations set forth in Paragraphs 151 and 152 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraphs 151 and 152 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 151-152 refer to the transcript of a Congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

153-154. Ivax and IPI deny the allegations set forth in Paragraphs 153 and 154 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraphs 153 and 154 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

**VII. THE FEDERAL GOVERNMENT HAS SPECIFICALLY DIRECTED
DEFENDANTS TO REPORT ACCURATE PRICING DATA**

155-156. Ivax and IPI deny the allegations set forth in Paragraphs 155 and 156 to the extent they are directed at Ivax and IPI. To the extent the allegations in

Paragraphs 155 and 156 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

157. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 157, and on that basis deny them. To the extent the allegations in Paragraph 157 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

158. Ivax and IPI deny the allegations set forth in Paragraph 158 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 158 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

VIII. DEFENDANTS' CONDUCT WAS INTENTIONALLY IN DISREGARD OF ESTABLISHED LAW

159-160. Ivax and IPI deny knowledge or information to form a belief as to the truth of the allegations in Paragraphs 159 through 160, and on that basis deny them.

161-164. Ivax and IPI deny the allegations set forth in Paragraphs 161 through 164 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraphs 161 through 164 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. except Ivax and IPI.

165. Ivax and IPI deny knowledge or information to form a belief as to the truth of the allegations in Paragraphs 165, and on that basis deny them.

166. Ivax and IPI deny the allegations set forth in Paragraph 166 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 166 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

IX. HARM TO IOWA AND ITS CITIZENS

167-171. Ivax and IPI deny the allegations set forth in Paragraphs 167 through 171 to the extent they are directed at Ivax and IPI. Specifically, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegation that the “Iowa Medicaid Program spent over \$1.6 billion for defendants’ drugs between 1992 and 2005 alone.” To the extent the allegations in Paragraphs 167 through 171 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

172-177. With respect to the allegations in Paragraphs 172 through 177, Ivax and IPI admit that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein. To the extent the remaining allegations in Paragraphs 172 through 177 or Exhibit B are directed at Ivax and IPI, Ivax and IPI deny them. Specifically, Ivax and IPI deny that they “routinely submitted false prices” to pricing compendia. Ivax and IPI further deny the characterization of “spread” in Paragraphs 172 through 177 and Exhibit B. To the extent the allegations in Paragraphs 172 through 177 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

X. ALLEGATIONS PARTICULAR TO IOWA AND THE INDIVIDUAL DEFENDANTS

178. Ivax and IPI deny the allegations set forth in Paragraph 178 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 178 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

179. Ivax and IPI deny the allegations set forth in Paragraph 179 to the extent they are directed at Ivax and IPI, except Ivax and IPI admit that they contract with purchasers sometimes included discounts. To the extent the allegations in Paragraph 179 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

180. Ivax and IPI deny the allegations set forth in Paragraph 180 to the extent they are directed at Ivax and IPI. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

181-410. The allegations in Paragraphs 181 through 410 are directed to other Defendants and require no response from Ivax and IPI. To the extent a response is deemed to be required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 181 through 410.

411. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 411 or its footnote or exhibit referenced therein.

412. Ivax and IPI deny the allegations in Paragraph 412 and the exhibit referenced therein.

413. Ivax and IPI deny the allegations in Paragraph 413.

414. Ivax and IPI deny the allegations in Paragraph 414 and the exhibit referenced therein. Specifically, Ivax and IPI deny that the reported AWP was “intentionally false and misleading” and that Iowa reimbursed “based on false and misleading wholesale price information.” To the extent that the allegations in Paragraph 414 refer to a Ivax or IPI document, Ivax and IPI deny any characterization or inference resulting from the Plaintiff’s citation. Ivax and IPI deny that Plaintiff has accurately characterized the findings, opinions, statements, or conclusions of the document.

415. Ivax and IPI deny the allegations in Paragraph 415. To the extent that the allegations in Paragraph 415 refer to a Ivax or IPI document, Ivax and IPI deny any characterization or inference resulting from the Plaintiff’s citation. Ivax and IPI deny that Plaintiff has accurately characterized the findings, opinions, statements, or conclusions of the document.

416. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraphs 416 that there was no FUL for Buspirone 10 mg tablet in “until Deceber 2002.” Ivax and IPI deny the remaining allegations in Paragraph 416, and on that basis deny them.

417. Ivax and IPI deny knowledge or information sufficient to form a belief as to the FUL for Buspirone 10 mg tablet on December 1, 2002. Ivax and IPI also deny the remaining allegations in Paragraph 417.

418. Ivax and IPI deny knowledge or information sufficient to form a belief as to the unit price for Buspirone 10 mg tablet in “April 2003.” Ivax and IPI also deny the remaining allegations in Paragraph 418.

419. Ivax and IPI deny the allegations in Paragraph 419, except Ivax and IPI admit that one or both have been named as Defendants in lawsuits filed by the States of Alabama, Alaska, Florida, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, Mississippi, South Carolina, Texas, Wisconsin, the City of New York and 42 New York Counties. Ivax and IPI specifically deny that there is any basis for those lawsuits or that they have been involved in any “wrongdoing.”

420. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 420, and on that basis deny them. Ivax and IPI specifically deny any allegation that it reported “inflated and false wholesale pricing information.”

421. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 421. Ivax and IPI specifically deny any any characterization of “spread.”

422. Ivax and IPI admit that Ivax Corporation has disclosed that it cooperated with the House Committee and Commerce’s “investigation into certain industry . . .

practices regarding AWP.” Ivax and IPI deny the remaining allegations of Paragraph 422 and specifically deny that there is any basis for such an investigation as to Ivax and IPI.

423. Ivax and IPI admit that they have been named as defendants in certain lawsuits filed by the Office of Attorneys General of certain states. Ivax and IPI deny the remaining allegations of Paragraph 423 and specifically deny that there is any basis for such suits.

424. Ivax and IPI admit that Ivax Corporation has disclosed that “the outcome of [certain] investigations could include the imposition of substantial fines, penalties” or other remedies. Ivax and IPI deny the remaining allegations of Paragraph 424 and specifically deny that there is any basis for such investigations as to Ivax and IPI.

425-613. The allegations in Paragraphs 425 through 613 are directed to other Defendants and require no response from Ivax and IPI. To the extent a response is deemed to be required, Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 425 through 613.

XI. DAMAGES TO IOWA MEDICAID PROGRAMS

614-616. Ivax and IPI deny knowledge or information sufficient to form a belief as to the truth of the allegation that Iowa’s Medicaid program “spent over \$1.6 billion for defendants’ drugs in state and federal dollars from 1992 through 2005 alone.” Ivax and IPI specifically deny the remaining allegations of Paragraphs 614 through 616 to the extent they are directed to Ivax and IPI. To the extent the allegations in Paragraphs 614

through 616 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

XII. FRAUDULENT CONCEALMENT

617-632. To the extent the allegations in Paragraphs 617 through 632 are directed at Ivax and IPI, Ivax and IPI deny them. Ivax and IPI further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 617 through 632 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 630 refer to *The Pink Sheet*, that document speaks for itself, and any characterizations thereof are denied.

COUNT I

VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)

633. In response to Paragraph 633, Ivax and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 632.

634-642. To the extent the allegations in Paragraphs 634 through 642 are directed at Ivax and IPI, Ivax and IPI state that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, Ivax and IPI deny the allegations to the extent they relate to Ivax and IPI. To the extent the allegations

in Paragraphs 634 through 642 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

COUNT II

BREACH OF CONTRACT

643. In response to Paragraph 643, Ivax and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 642.

644-651. To the extent the allegations in Paragraphs 644 through 651 are directed at Ivax and IPI, Ivax and IPI state that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, Ivax and IPI deny the allegations as they relate to Ivax and IPI. To the extent the allegations in Paragraphs 644 through 651 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth.

COUNT III

**IOWA CONSUMER FRAUD ACT
(Iowa Code § 714.16)**

652. In response to Paragraph 652, Ivax and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 651.

653. To the extent the allegations in Paragraph 653 and the exhibits referenced therein are directed at Ivax and IPI, Ivax and IPI deny them. To the extent the allegations in Paragraph 653 are directed at parties other than Ivax and IPI, Ivax and IPI deny

knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 653 refers to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

654-657. To the extent the allegations in Paragraphs 654 through 657 and the sub-parts thereto are directed at Ivax and IPI, Ivax and IPI deny them. To the extent the allegations in Paragraphs 654 through 657 and the sub-parts thereto are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 654 through 657 and the sub-parts thereto refer to statutes, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 654 through 657 and the sub-parts thereto contain legal conclusions, no response is required.

COUNT IV

FRAUD

658. In response to Paragraph 658, Ivax and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 657.

659-662. To the extent the allegations in Paragraphs 659 through 662 and the exhibits referenced therein are directed at Ivax and IPI, Ivax and IPI deny them. To the extent the allegations in Paragraphs 659 through 662 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 659 through 662 refer to Iowa law, those sources speak for themselves, and any characterizations thereof are denied. To the

extent the allegations in Paragraphs 659 through 662 contain legal conclusions, no response is required.

COUNT VIII

UNJUST ENRICHMENT

663. In response to Paragraph 663, Ivax and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 662.

664-666. To the extent the allegations in Paragraphs 664 through 666 are directed at Ivax and IPI, Ivax and IPI deny them. To the extent the allegations in Paragraphs 664 through 666 are directed at parties other than Ivax and IPI, Ivax and IPI deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 664 through 666 contain legal conclusions, no response is required.

PRAYER FOR RELIEF

667-675. Ivax and IPI deny that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 667-675 of the Complaint.

Ivax and IPI deny all allegations in the Complaint (including headings and sub-headings) not specifically admitted above.

AFFIRMATIVE DEFENSES

Ivax and IPI set forth the following affirmative and other defenses. Ivax and IPI do not intend hereby to assume the burden of proof with respect to those matter as to which, pursuant to applicable law, Plaintiff bears the burden. Ivax and IPI reserve the right to assert in the future such other and further defenses as may become available or apparent during pretrial proceedings.

First Affirmative Defense

Plaintiff fails to state a claim upon which relief may be granted.

Second Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because they do not rely on any alleged misrepresentations or fraud by Ivax or IPI. Plaintiff knew that providers could obtain drugs manufactured by Ivax or IPI at prices below AWP prior to the relevant time period stated in the Complaint.

Third Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, ratification and waiver.

Fourth Affirmative Defense

Plaintiff fails to state with particularity facts to support claims of fraudulent conduct or fraudulent concealment.

Fifth Affirmative Defense

Ivax and IPI acted at all times in accordance with standard industry practice and in the good faith belief that its actions were lawful. Ivax and IPI also acted in

reasonable reliance on statements by government officials that the industry practices complained of herein were lawful.

Sixth Affirmative Defense

Statements or actions by Ivax or IPI were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiff.

Seventh Affirmative Defense

To the extent Plaintiff obtains recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against Ivax and IPI based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

Eighth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Ivax or IPI in judicial, legislative, or administrative proceedings of any kind or at any level of government.

Ninth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiff's claims.

Tenth Affirmative Defense

Neither Ivax's nor IPI's actions violated the law, and were permitted by applicable federal law.

Eleventh Affirmative Defense

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, and the Prescription Drug, Improvement and Modernization Act of 2003, including all amendments to the same and all regulations promulgated thereunder.

Twelfth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a "consumer" within the meaning of the Iowa Consumer Fraud Act.

Thirteenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a "person" within the meaning of the Iowa Consumer Fraud Act.

Fourteenth Affirmative Defense

Some or all of Plaintiff's claims against Ivax and IPI arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

Fifteenth Affirmative Defense

Ivax and IPI deny that Plaintiff has a valid consumer protection claim against Ivax and IPI under the Iowa Consumer Fraud Act. However, if such claim is found to exist, Ivax and IPI plead all available defenses under the Act.

Sixteenth Affirmative Defense

To the extent that Plaintiff attempts to seek equitable relief against Ivax and IPI, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

Seventeenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

Eighteenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by Ivax and IPI after the filing of the Complaint.

Nineteenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

Twentieth Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred, in whole or in part, due to their failure to join indispensable parties.

Twenty-First Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred, in whole or in part, because Plaintiff has not suffered damages as a result of the matters alleged in the Complaint.

Twenty-Second Affirmative Defense

Plaintiff's claims are barred, in whole or in part, (1) because Plaintiff failed to mitigate damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Ivax and IPI; (2) because Plaintiff would be unjustly enriched if allowed to recover any

portion of the damages alleged in the Complaint; and (3) because damages are speculative and remote and because of the impossibility of ascertaining and allocating alleged damages.

Twenty-Third Affirmative Defense

Ivax and IPI are entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

Twenty-Fourth Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Iowa Constitution.

Twenty-Fifth Affirmative Defense

Plaintiff's claims against Ivax and IPI are preempted by the Commerce Clause and/or the dormant Commerce Clause of the United States Constitution.

Twenty-Sixth Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred, in whole or in part, because they violate the rights of Ivax and IPI under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Iowa Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Twenty-Seventh Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred because Plaintiff and/or its agents knew and were aware that AWP was not an actual average of wholesale prices or

the actual acquisition cost of pharmaceuticals. Legal and equitable principles preclude this action for damages and injunctive relief.

Twenty-Eighth Affirmative Defense

The claims alleged herein, based on the facts alleged, are barred in whole or in part by Plaintiff's own negligence or gross negligence and the doctrines of comparative and/or contributory negligence. Among other things, the claims disregard Iowa's obligations under federal law.

Twenty-Ninth Affirmative Defense

Plaintiff's prayers for relief in the form of restitution are barred, in whole or in part, because Ivax and IPI did not retain any money belonging to Plaintiff as a result of any alleged overpayments.

Thirtieth Affirmative Defense

Plaintiff has failed to plead with particularity allegations of fraud by Ivax and IPI contained in the Complaint.

Thirty-First Affirmative Defense

Plaintiff's claims for fraud and fraudulent concealment are barred because the Plaintiff cannot predicate a claim for fraud on reliance by a third party.

Thirty-Second Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred because Plaintiff lacks standing or capacity to bring the some or all of the claims asserted against Ivax and IPI under Iowa law.

Thirty-Third Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred in whole or in part by the doctrine of voluntary payment.

Thirty-Fourth Affirmative Defense

Plaintiff's claims against Ivax and IPI for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

Thirty-Fifth Affirmative Defense

Plaintiff's claims against Ivax and IPI for unjust enrichment are barred because the Complaint does not allege that Defendants received any payment or property from the Plaintiff.

Thirty-Sixth Affirmative Defense

Plaintiff's claims against Ivax and IPI for injunctive relief are barred by the doctrines of *in pari delicto* and/or unclean hands.

Thirty-Seventh Affirmative Defense

Plaintiff's claims against Ivax and IPI are misjoined with Plaintiff's claims against other Defendants and must be severed.

Thirty-Eighth Affirmative Defense

Any damages recovered by the Plaintiff must be limited by any applicable statutory ceiling on recoverable damages.

Thirty Ninth Affirmative Defense

To the extent punitive damages are sought, Plaintiff's punitive damages claims against Ivax and IPI (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for

punitive damages against Ivax and IPI; (3) cannot be sustained because the laws regarding the standards for determining liability for, and the amount of, punitive damages fail to give Ivax and IPI prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of the due process rights of Ivax and IPI as guaranteed by the Fifth and the Fourteenth Amendments to the United States Constitution; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate the due process and equal protection rights of Ivax and IPI as guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and be improper under the Iowa Constitution and Iowa common law.

Fortieth Affirmative Defense

Plaintiff fails to allege facts or a cause of action against Ivax and IPI sufficient to support a claim for prejudgment interest or any other relief.

Forty-First Affirmative Defense

Plaintiff has not suffered, and will not suffer, any injuries to a legally protected or cognizable interest by reason of the conduct of Ivax and IPI as alleged in the Complaint.

Forty-Second Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred because Ivax and IPI has complied with all applicable regulations of the federal and state governments.

Forty-Third Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of intervening or superseding conduct of third parties.

Forty-Fourth Affirmative Defense

Plaintiff's claims against Ivax and IPI are barred, in whole or in part, because Ivax and IPI did not make any false statements to the Plaintiff. As to any statement asserted against Ivax and IPI that Plaintiff alleges to be false or misleading, Ivax and IPI had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Forty-Fifth Affirmative Defense

Plaintiff fails to allege facts or a cause of action sufficient to support a claim against Ivax and IPI for compensatory damages, attorneys' fees, enhanced damages, treble damages and/or legal fees or costs.

Forty-Sixth Affirmative Defense

Ivax and IPI adopt by reference any additional applicable defense pled by any other Defendant not otherwise pled herein.

Forty-Seventh Affirmative Defense

Ivax and IPI hereby give notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its Answer to assert such defense

Respectfully submitted,

Dated: September 18, 2008

/s/ Jenny G. Levy

Jenny G. Levy (admitted *pro hac vice*)

Patrick M. Bryan (admitted *pro hac vice*)

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the ANSWER AND AFFIRMATIVE DEFENSES OF IVAX CORPORATION AND IVAX PHARMACEUTICALS, INC. TO THE STATE OF IOWA'S COMPLAINT was delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on September 18, 2008, for posting and notification to all parties.

/s/ Patrick M. Bryan
Patrick M. Bryan